

62 102. The method of claim 101, wherein said second formulation comprises a compound selected from the group consisting of antifungal agents, pharmaceutically acceptable aqueous vehicles, pharmaceutically acceptable solid vehicles, mucolytic agents, antibacterial agents, anti-inflammatory agents, immunosuppressants, dilators, vaso-constrictors, steroids, and therapeutic compounds.

33 cont 103. *44* The method of claim 102, said method comprising, after said mucoadministration, prophylactically mucoadministering to said human a prophylactic formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said prophylactic formulation comprising an antifungal agent.

71 104. *90* The method of claim 103, wherein said prophylactic mucoadministration comprises direct mucoadministration.

REMARKS

Claims 1-20 of the above-identified application have been rejected. Applicant has cancelled claims 8, 14, and 15 without prejudice, and added claims 51-104 herein. Thus, claims 1-7, 9-13, 16-20, and 51-104 are pending. In addition, Applicant has amended claims 1 and 7 herein to more particularly point out and distinctly claim the subject matter Applicant regards as his invention. These amendments are supported throughout the specification as originally filed. For example, original claim 14 recites that the mucoadministration comprises orally applying the formulation to the digestive tract of the mammal, and original claim 37 recites that the duration is greater than about 30 days. Thus, these amendments do not add new matter. In light of these amendments and the remarks below, Applicant respectfully submits that the pending claims are in condition for allowance and free from the prior art including Sait *et al.*, *Digestive Diseases*, 15(11):993-1002 (1970).

Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Eisen (U.S. Patent No. 5,310,545) or Ramos *et al.* (*Nutr. Cancer*, 28(2):212-217 (1997)).

Specifically, the Examiner stated that Eisen teaches the use of a combination containing steroids and antifungal agents to treat inflammatory disorders such as mucositis, and that Ramos *et al.* teach on oral administration of short-chain fatty acids used to reduce intestinal mucositis.

Applicant respectfully disagrees. The present claims recite treating or preventing non-invasive fungus-induced intestinal mucositis. The Eisen reference discloses swishing mouthwash to treat inflammatory diseases of the mouth. At no point does the Eisen reference disclose the treatment of any intestinal condition, let alone a non-invasive fungus-induced intestinal mucositis condition. In addition, the Eisen reference fails to suggest any method that can be used to treat or prevent non-invasive fungus-induced intestinal mucositis. In fact, the Eisen reference uses the term "intestinal" only twice, and in both cases the term is used to indicate that a preferred mouthwash should contain an antifungal agent that is poorly absorbed by mucosa of the intestinal tract. See, column 4, lines 41-49 of the Eisen reference. In light of these deficiencies, Applicant respectfully submits that the Eisen reference does not render the presently claimed invention obvious.

The Ramos *et al.* reference also fails to suggest treating or preventing non-invasive fungus-induced intestinal mucositis as presently claimed. In fact, the Ramos *et al.* reference discloses administering a short-chain fatty acid solution to mice such that inflammation and necrosis caused by cytarbine administration is reduced. The present claims recite treating or preventing non-invasive fungus-induced intestinal mucositis, not inflammation caused by cytarbine administration. In addition, claim 1 recites using a duration that is greater than about 30 days to reduce or eliminate non-invasive fungus-induced intestinal mucositis. At no point does the Ramos *et al.* reference suggest using such a duration to reduce or eliminate non-invasive fungus-induced intestinal mucositis. Again, the Ramos *et al.* reference simply discloses administering a short-chain fatty acid solution to reduce inflammation caused by cytarbine administration. Thus, Applicant respectfully submits that the Ramos *et al.* reference does not render the presently claimed invention obvious.

In light of the above, Applicant respectfully requests the withdrawal of the rejections under 35 U.S.C. §103(a).

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CONCLUSION

Applicant submits that claims 1-7, 9-13, 16-20, and 51-104 are in condition for allowance, which action is requested. Filed herewith is a check in payment of the excess claims fees required by the above amendments and Petition for Automatic Extension with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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